

CLAIMS

We claim:

1. A multi-valent immunogenic composition for conferring protection in a host against disease caused by *Bordetella pertussis*, *Clostridium tetani*, *Corynebacterium diphtheriae*, *Haemophilus influenzae*, poliovirus and/or Hepatitis B virus
2. A multi-valent immunogenic composition for conferring protection in a host against disease caused by *Bordetella pertussis*, *Clostridium tetani*, *Corynebacterium diphtheriae*, *Haemophilus influenzae*, poliovirus and/or Hepatitis B virus comprising:
 - (a) pertussis toxoid and filamentous haemagglutinin in purified form,
 - (b) tetanus toxoid,
 - (c) diphtheria toxoid,
 - (d) inactivated polio virus,
 - (e) Hepatitis B surface Ag, and
 - (f) a conjugate of a carrier molecule selected from tetanus toxoid and diphtheria toxoid and a capsular polysaccharide of *Haemophilus influenzae* type B.
3. The immunogenic composition of claim 2 formulated as a vaccine for *in vivo* administration to the host wherein the individual components of the composition are formulated such that the immunogenicity of individual components is not impaired by other individual components of the composition.
4. The immunogenic composition of claim 2 formulated as a vaccine for *in vivo* administration to the host, which confers an antibody titer superior to the criterion for seroprotection for each antigenic component for an acceptable percentage of human subjects.
5. The immunogenic composition of claim 3 further comprising an adjuvant.
6. The immunogenic composition of claim 5 wherein the adjuvant is aluminum salts .
7. The immunogenic composition of claim 3 wherein said pertussis toxoid is present in an amount of about 5 to about 30 ug and said filamentous hemagglutinin is present in an amount of about 5 to about 30 ug, in a single dose.

8. The immunogenic composition of claim 7 containing about 25 ug of pertussis toxoid and about 25 ug of filamentous haemagglutinin in a single human dose.
9. The vaccine of claim 7 wherein said diphtheria toxoid is present in an amount of about 5 to about 50 LF and said tetanus toxoid is present in an amount of about 5 to about 50 LF.
10. The vaccine of claim 9 wherein said diphtheria toxoid is present in an amount of about 30 LF and said tetanus toxoid is present in an amount of about 10 LF.
11. The vaccine of claim 3 wherein said inactivated polio virus comprises a mixture of inactivated polio virus types 1, 2 and 3.
12. The vaccine of claim 11 wherein said inactivated polio virus comprises a mixture of inactivated poliovirus types 1, 2 and 3 in the proportions:
about 20 to about 50 D antigen units of poliovirus type 1;
about 4 to about 10 D antigen units of poliovirus type 2; and
about 8 to about 40 D antigen units of poliovirus type 3 in a single human dose.
13. The vaccine of claim 12, wherein said inactivated poliovirus comprises a mixture of inactivated poliovirus types 1, 2 and 3 in the proportions:
about 40 D antigen units of poliovirus type 1;
about 8 D antigen units of poliovirus type 2; and
about 32 D antigen units of poliovirus type 3 in a single human dose.
14. The vaccine of claim 3 wherein said conjugate comprises a conjugate of tetanus toxoid or diphtheria toxoid and polyribose ribitol phosphate (PRP) of *Haemophilus influenzae* type b.
15. The vaccine of claim 3 wherein the Hepatitis B surface antigen is separated from other components in a dual-chamber syringe and is reconstituted during the administration to the subject
16. A multi-valent vaccine composition comprising, per 0.5 ml dose,
25 ug pertussis toxoid;
25 ug filamentous hemagglutinin;
30 LF diphtheria toxoid;
10 LF tetanus toxoid;
40 D antigen units poliovirus type 1;

8 D antigen units poliovirus type 2;
32 D antigen units poliovirus type 3;
10 ug Haemophilus influenzae type b polysaccharide covalently bound to 20 ug tetanus toxoid;
5 ug Hepatitis B Surface Ag;
20 μ Moles phosphates
5 μ Moles carbonates
0.125 ml tris 50mMolaire buffer comprising saccharose in 42,5 %
and 0.306 mg aluminum hydroxide.

- a
17. A method of immunizing a human host against disease caused by infection by *Bordetella pertussis*, *Clostridium tetanae*, *Corynebacterium diphtheriae*, *Haemophilus influenzae*, poliovirus and/or Hepatitis b virus, which method comprises administering to the host an immunoeffective dose of the immunogenic composition of claim 1.
18. The method of claim 17, wherein the host is a child.
19. A multivalent vaccine of claim 16 wherein the aluminium is in a quantity of 0.356 mg and wherein the Hepatitis B Surface Ag is separated from other components in a multi-chamber syringe.
20. A multivalent vaccine of claim 16 wherein the Hepatitis B Surface Ag is adsorbed on aluminium salts.
- add a!